



Illinois Office of Health Information Technology



ILHIE Authority Data Security and Privacy Committee

GENETIC TESTING WORK GROUP PROGRESS REPORT

July 27, 2012

MAIN GOALS

1. Retain protection of privacy of genetic information.
2. Allow health care providers access to genetic information to facilitate health care.
3. Retain consistency with Federal health information privacy law (HIPAA) and Federal Genetic Information Non-Discrimination Act (GINA).
4. Ensure practicality of implementation of the Illinois Health Information Exchange in light of the Illinois Genetic Privacy Act (GIPA).

GIPA ISSUES TO BE RESOLVED

1. Clarify the scope of genetic information that is subject to GIPA.
2. Clarify rules for lawful disclosure of genetic information that is subject to GIPA (i.e. initial transmission of information to ILHIE).
3. Clarify rules for lawful re-disclosure of genetic information that is subject to GIPA (i.e. further transmission of information from ILHIE).
4. Underscore the need for state-wide uniformity of rules governing protection of genetic information that is subject to GIPA (i.e. home rule).

GIPA ISSUES TO BE RESOLVED: #1

CLARIFY THE SCOPE OF GENETIC INFORMATION THAT IS SUBJECT TO GIPA.

Section 15. Confidentiality of genetic information.

(a) Except as otherwise provided in this Act, **genetic testing and information derived from genetic testing** is confidential ...

and

may be released only to the individual tested and to persons specifically authorized, in writing in accordance with Section 30, by that individual to receive the information.

WHAT IS THE SCOPE OF “DERIVED” INFORMATION?

GIPA ISSUES TO BE RESOLVED: #1

CLARIFY THE SCOPE OF GENETIC INFORMATION THAT IS SUBJECT TO GIPA.

Section 15. Confidentiality of genetic information.

- (d) Results of genetic testing that indicate that the individual tested is at the time of the test **afflicted** with a disease, whether or not currently symptomatic,
are not subject to the confidentiality requirements of this Act.

WHAT DOES IT MEAN TO BE “AFFLICTED” WITH A DISEASE?

GIPA ISSUES TO BE RESOLVED: #2

CLARIFY RULES FOR LAWFUL DISCLOSURE OF GENETIC INFORMATION THAT IS SUBJECT TO GIPA

Section 30. Disclosure of the person tested and test results.

- (a) No person may disclose or be compelled to disclose the identity of any person upon whom a genetic test is performed or the results of a genetic test in a manner that permits identification of the subject of the test, except to the following persons:
- (3) An authorized agent or employee of a health facility or health care provider **if the health facility or health care provider itself is authorized** to obtain the test results, the agent or employee provides patient care, and the agent or employee has a need to know the information in order to conduct the tests or provide care or treatment.

GIPA ISSUES TO BE RESOLVED: #2

CLARIFY RULES FOR LAWFUL DISCLOSURE OF GENETIC INFORMATION THAT IS
SUBJECT TO GIPA

Section 30. Disclosure of the person tested and test results.

No person may disclose or be compelled to disclose the identity of any person ... except to ...

a health facility or health care provider **if** the health **facility** or health care **provider** **itself is authorized** to obtain the test results...

WHAT DOES IT MEAN TO BE “ITSELF AUTHORIZED?”

GIPA ISSUES TO BE RESOLVED: #2

CLARIFY RULES FOR LAWFUL DISCLOSURE OF GENETIC INFORMATION THAT IS
SUBJECT TO GIPA

Section 30. Disclosure of the person tested and test results.

WHAT DOES IT MEAN TO BE “ITSELF AUTHORIZED?”

Alternative 1: Implied authorization for disclosure of confidential information for treatment purposes, consistent with HIPAA/GINA;

Alternative 2: Requirement for an express written authorization for disclosure, consistent with the language in Section 15(a).

GIPA ISSUES TO BE RESOLVED: #3

CLARIFY RULES FOR LAWFUL RE-DISCLOSURE OF GENETIC INFORMATION THAT IS SUBJECT TO
GIPA

Section 35. Disclosure by person to whom results have been disclosed.

No person to whom the results of a test have been disclosed may disclose the test results to another person **except as authorized by Section 30.**

**IS ILHIE AN “AGENT” OF A FACILITY OR PROVIDER
THAT IS “ITSELF AUTHORIZED?”**

Same two alternative interpretations above, and more

GIPA ISSUES TO BE RESOLVED: #3

CLARIFY RULES FOR LAWFUL RE-DISCLOSURE OF GENETIC INFORMATION THAT IS
SUBJECT TO GIPA.

Section 30. Disclosure of the person tested and test results.

No person may disclose or be compelled to disclose the identity of
any person ... except to ...

Any person designated in a **specific** written legally effective release of
the test results executed by the subject of the test or the subject's legally
authorized representative.

GIPA ISSUES TO BE RESOLVED: #3

**CLARIFY RULES FOR LAWFUL RE-DISCLOSURE OF GENETIC INFORMATION THAT IS
SUBJECT TO GIPA.**

WHAT IS A SPECIFIC, LEGALLY EFFECTIVE RELEASE?

45 CFR 164.508(c). A valid, HIPAA compliant authorization must contain...

- (i) A “specific and meaningful” description of the information to be disclosed;
- (ii) The name or other specific identification of the person(s), or class of persons, to whom disclosure may be made;
- (iii) Expiration date or event, other than “none.”

GIPA ISSUES TO BE RESOLVED: #4

UNDERScore THE NEED FOR STATE-WIDE UNIFORMITY OF RULES GOVERNING PROTECTION OF GENETIC INFORMATION THAT IS SUBJECT TO GIPA.

Section. 50. Home rule

“Any home rule unit of local government, any non-home rule municipality, or any non-home rule county within the unincorporated territory of the county may enact ordinances, standards, rules, or regulations that protect genetic information and genetic testing in a manner or to an extent equal to or greater than the protection provided in this Act...”